DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and the Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming joint meeting of two public advisory committees of the Food and Drug Administration (FDA). At least one portion of the joint meeting will be closed to the public.

Name of *Committees:* Transmissible Spongiform Encephalopathies Advisory Committee and the Blood Products Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 16, 2002, from 1 p.m. to 4:30 p.m.; and on January 17, 2002, from 8 a.m. to 5:15 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 17, 2002, the committees will listen to updates on the "Revised FDA Guidance on Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"

document, and other related topics. For the purpose of further evaluating the adequacy of our present blood deferral recommendations, the committee will then discuss the effectiveness of measures taken to protect humans from foodbome exposure to the bovine spongiform encephalopathy (BSE) agent in countries with BSE.

Procedure: On January 17, 2002, from 8 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 11, 2002. Oral presentations from the public will be scheduled between approximately 1:20 p.m. and 2:20 p.m. on January 17, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 11, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On January 16, 2002, from 1 p.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

FDA regrets that it was unable to publish this notice 15 days prior to the January 16 and 17, 2002, Joint Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and the Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Joint Meeting of the Transmissible Spongiform Encephalopathies Advisory Committee and the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 12/26/01

December 26, 2001.

Linda A. Suydam

Linda A. Suydam,
Senior Associate Commissioner.

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